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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,658	05/30/2001	Barbara P. Wallner	10248/7014	3397

7590 09/28/2004

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/744,658	Applicant(s) WALLNER, BARBARA P.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8-12,14-16 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8,12,14-16 and 24 is/are rejected.
- 7) ☒ Claim(s) 9-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20040826</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 26, 2004 has been entered.

2. Applicant's election of the method and composition using the -B(D₁)(D₂) compounds of claim 7 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 22 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 7.

3. In claims 1 and 24, the Y group formula, and especially the subscripts attached to the R groups, is nearly illegible. It is requested in any future amendment to the claims that the Y group formulas be made larger and/or clearer.

4. It should be noted that claims 22 and 23 are currently dependent upon canceled claim 7.

5. Instant claims 9-11 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/097,376 because the '376 application, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed invention. Instant claims 1, 8, 12, 14-16, and 24 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/097,376 because the '376 application, under the test of 35 U.S.C. 112, first paragraph, does not disclose the compounds of instant claims 1 and 24 which

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comprise an $[X]_m$ group or which do not comprise a C=O group attached to the ring, and does not disclose the phosphonate groups of claims 1 and 24 in which J can be any number of C, H, O, S, or N atoms.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 98/25644. The WO Patent Application '644 teaches co-administering GLP-2 with DPP-IV inhibitors in order to increase the mass and length, to promote the growth, and to enhance the function of the small and/or large intestine. In particular, the drug combination is used, e.g., to promote the healing and regrowth of injured, ulcerated, or inflamed intestinal mucosa, and to treat or prevent gastrointestinal disorders such as celiac disease, post-infectious villous atrophy, and short gut syndrome. Pro-boroPro is particularly preferred as a DPP-IV inhibitor. The compounds are administered subcutaneously or intravenously, i.e. parenterally. See, e.g., page 2, line 30 - page 3, line 10; page 4, lines 13-23; page 9, lines 35-36; and claims 7, 16, and 17.

8. Claims 1, 8, 12, 14-16, and 24 are rejected under 35 U.S.C. 102(a) as being anticipated by the WO Patent Application 99/38501. The WO Patent Application '501 teaches treating atherosclerosis by administering DPIV inhibitors. The WO Patent Application '501 also teaches agonizing the action of GLP-2 by administering DPIV inhibitors. Preferred inhibitors have a K_i for DPIV inhibition of 1 nM or less, and comprise boroproline residues. Administration can be in amounts of from 0.01-2000 mg/adult subject/day, and can be oral or parenteral. See, e.g., the Abstract; page 3, line 31; page 5, line 24; page 6, lines 3-15; page 30, line 3 - page 32, line 15;

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page 33, line 13 - page 35, line 5; page 37, lines 5-9; and page 40, lines 6-8. With respect to instant claim 12, because the same DPIV inhibitors are being administered to the same subjects by the same method steps, inherently substrate activity will be altered in the WO Patent Application '501 to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the method of the WO Patent Application '501 and Applicant's claimed method to shift the burden to Applicant to provide evidence that the claimed invention is unobviously different than that of the WO Patent Application '501.

9. Applicant's arguments filed August 26, 2004 have been fully considered but they are not persuasive.

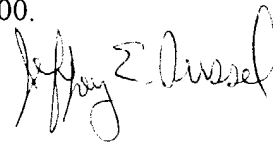
Claim 24 is rejected over the WO Patent Application 98/25644. The "consisting essentially of" language used in instant claim 24 excludes from the scope of Applicant's claim only those prior art components which would materially affect the basic and novel characteristics of Applicant's claimed invention. See MPEP 2111.03. Applicant has not demonstrated that the GLP-2 of the WO Patent Application '644 would affect the basic and novel characteristics of Applicant's claimed invention, and therefore Applicant's claim does not exclude the co-administration of GLP2. Note that in interpreting the effect which "consisting essentially of" has on Applicant's claimed invention, it is irrelevant as to whether the additional component is essential for the purposes of the prior art reference.

10. Claims 9-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in dark ink, appearing to read "Jeffrey E. Russel". The signature is fluid and cursive, with the first name "Jeffrey" and last name "Russel" clearly distinguishable.

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

September 24, 2004